

### Remarks

Claims 1-13 were examined and are pending in the present application. By this amendment, Claims 1 and 9-13 are amended, leaving Claims 1-13 pending.

### **Objections to the Specification**

The specification was objected to on the basis that following certain occurrences of the term "IFN," there appeared boxes. These boxes were intended to represent the Greek symbol for gamma, "γ," as shown, for example, in Example 7 (where the symbol correctly appears in the heading of the example, but the character was mis-printed in the body of the example.

Replacement paragraphs have been submitted, thus mooted this objection.

### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 9-11 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite, because they did not specify to what subject matter the body weight limitation pertained. Claim 1 is directed to a method of treating animals by administering the compound. It should have been clear that, with respect to Claim 1, the compound was to be administered to the animal, and it should also have been clear that the body weight was that of the animal to which the compound was administered. However, to facilitate allowable subject matter, Claim 1 has been amended to clarify that the compound is administered to the animal, and Claims 9-11 have been amended to state that the body weight is the body weight of the animal (to which the compound is administered).

Claims 9-11 were also rejected for using the phrase "the range," and the Examiner suggested amending the claims to replace "the" with "a." The claims have been amended as suggested by the Examiner.

In view of the above amendments, Applicant respectfully submits that each of these objections may properly be withdrawn.

#### **Rejections under 35 U.S.C. § 102(b)**

Claims 1-10 and 12-13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Aoyama et al. Claims 1-13 were rejected under 35 U.S.C. § 102(b) as anticipated by Wang.

#### **The Claimed Subject Matter**

Claim 1 as presently amended is directed to a method of preventing and/or treating asthma by administering a composition consisting essentially of a therapeutically effective dose of luteolin.

#### **Aoyama**

Aoyama discloses that the alcoholic extract obtained from the *Perilla* seed "contains one or more compounds selected from apigenin, chrysoeriol, luteolin and rosmarinic acid" (or "rosmarinic acid," according to the Derwent English Abstract).

Aoyama may teach unpurified alcoholic extracts obtained from the *Perilla* seed, which extracts include luteolin, among other compounds which may be effective at treating asthma. However, Aoyama does not teach or suggest compositions consisting essentially of luteolin.

Applicant therefore respectfully submits that Aoyama does not disclose what a therapeutic amount of any single compound in the disclosed extract may be, let alone what an

effective amount of luteolin might be. Accordingly, Aoyama does not disclose the subject matter of the claims as amended.

Wang

Wang discloses that luteolin is effective at treating bronchitis, and the various symptoms associated with bronchitis. While asthma is a symptom of bronchitis, bronchitis is not a symptom of asthma. Thus, a teaching that luteolin can treat the asthma associated with bronchitis does not necessarily lead one to the conclusion that all asthma patients, including those not suffering from bronchitis, would be effectively treated by luteolin.

It is not clear that bronchitis treatments are effective at treating asthma patients, except perhaps those suffering from asthma associated with bronchitis. Without a reference teaching that this type of association can be made, Applicants respectfully assert that the rejection is improper. Accordingly, it is believed that this ground of rejection should be withdrawn.

**Rejections under 35 U.S.C. § 103 (a)**

Claims 1-13 were rejected under 35 U.S.C. § 103 (a) as obvious over Aoyama alone, or Aoyama in view of Nagai, Park, Kimata, and Yamamoto. These rejections are respectfully traversed if applied to the amended claims.

It is submitted that Aoyama does not teach an effective dose of luteolin, or that the composition would be effective without the other components of the extract. On this basis alone, the instant claims, directed to a composition consisting essentially of luteolin, are not obvious over Aoyama.

Nagai teaches that luteolin inhibits histamine, but does not teach or suggest that it can be used to treat asthma.

Park teaches that luteolin-4'-O-glucoside is an inhibitor of interleukin-5. Park does not teach that luteolin itself, rather than its glucoside, would be an inhibitor of interleukin-5, or that luteolin would be effective in treating asthma.

Kimata teaches that luteolin inhibits mast cell activation by inhibiting calcium ion influx and PKC activation. However, Kimata does not teach that luteolin would be effective in treating asthma.

Yamamoto teaches that luteolin is an inhibitor of arachidonate lipoxenase, which is not particularly relevant to the claims. Yamamoto also teaches that the extract from 800 grams of perilla seeds, first extracted with hot hexane, then three times with hot ethanol, then with ethyl acetate (washed with water), and then subjected to silicon dioxide column chromatography, yields 240 mg of luteolin. It is unclear whether this complicated extraction protocol has any bearing whatsoever to the alcoholic extracts in Aoyama.

The most the secondary references teach is that luteolin, at some concentration, in a cellular assay, interacts with various receptors that may be implicated in a variety of disorders, without specifically disclosing asthma as a disorder that may be treated. Applicants submit that this teaching is not effective to render the claimed invention obvious.


Accordingly, it is asserted that the references, alone or in combination, do not render obvious the subject matter as presently claimed.

Conclusion

Claims 1-13 as amended herein are believed allowable, and an early notice to such effect is earnestly solicited. Should the Examiner have any questions or comments regarding the foregoing Amendment, he is urged to telephone the undersigned attorney.

Respectfully submitted,

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